DIA LEARNING

Signal Management in Pharmacovigilance

Virtual Live Training Course

24-27 November 2025 | 13:00-17:00 CET

Overview

This virtual live training course covers essential concepts of signal detection and signal management and provides guidance on how to apply these concepts at participants' function and their organisation, including the data mining techniques for large volume ADR data analysis.

The entire course is in line with the current guidelines on EU GVP Module IX – Signal management (rev. 1), Commission Implementing Regulation (EU) No. 520/2012, CIOMS VIII and relevant EMA guidelines.

This training is primarily developed based on EU legislation, but it also covers regulatory expectations for signal management in other countries.

Participants benefit from the hands-on experience of trainers who have worked for many years in signalling activities and are ready to not only explain the legislation, but also provide personal experience and most commonly followed practices that are often considered as industry standards.

Learning Objectives

At the conclusion of this virtual live training course, participants will be able to:

- Apply the essential concepts and principles of signal management in PV and implement or improve this process in their own organisation
- Compare different approaches to signal management that are followed by various organisations
- Operate and implement EVDAS into signal management process
- Follow the regulatory expectations at different geographic regions

Key Topics

- Signal Detection – Theory, methods, data mining, new trends
- Signal Management – Detection, validation, confirmation, analysis and prioritisation, assessment, and recommendation for action
- Regulatory expectations in the EU, US, Switzerland, Canada, Australia
- EVDAS introduction and implementation in signal management
- Strategy for implementation of signal management process in your own organisation (covering both small and large companies)

Who Will Attend

This virtual live training course is designed for professionals working in:

- Pharmacovigilance (including EU QPPVs)
- Drug Safety and Risk Management
- Signal Management and Safety Science
- Pharmacoepidemiology
- Information Technology
- Pharmacovigilance Consultancies and Service Providers
- Quality and Compliance

Course level: Intermediate, for professionals with 2-3 years (or more) of experience in Pharmacovigilance, or related functions who are working in PV around signal management.

Faculty

Jan Kolouch
CEO, Strategic PV Advisor
NextPV Services, Czech Republic

Calin Lungu
CEO
Drug Development Consulting Services, Luxembourg

Margarida Guimaraes
Scientific Administrator
European Medicines Agency, Netherlands

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE OF EXCELLENCE

Schedule-At-A-Glance

DAY 1

13:00 WELCOME AND INTRODUCTION

13:30 SESSION 1

SIGNAL DETECTION – THEORY, METHODS, DATA MINING, NEW TRENDS

- Terminology
- Sources of signals:
  - Traditional
  - Not (yet) traditional
  - Databases
- Group exercise on signal detection

15:00 BREAK

15:30 SESSION 1 (CONTINUED)

SIGNAL DETECTION – THEORY, METHODS, DATA MINING, NEW TRENDS

- Data mining techniques:
  - Proportional Reporting Ratio
  - Reporting Odds Ratio
  - Multi-item Gamma Poisson Shrinker (MGPS)
  - Bayesian Confidence Propagation Neural Network (BCPNN)
- Principles of data mining in spontaneous reporting system (SRS)
- Group exercise on data mining methods
- Recent developments in data mining
- Proactive and predictive signal detection
- Use of automation and AI

17:00 END OF DAY 1

DAY 2

13:00 SESSION 2

SIGNAL MANAGEMENT – DETECTION, TRIAGE, EVALUATION, FURTHER ACTION

- PV system overview
- Signal management process:
  - CIOMS
  - GVP Module IX
- Identification of sources and signal detection
- Group exercise on Periodic Safety Update Report (PSUR) data visualisation

15:00 BREAK

15:30 SESSION 2 (CONTINUED)

SIGNAL MANAGEMENT – DETECTION, TRIAGE, EVALUATION, FURTHER ACTION

- Signal validation/prioritisation
- Signal assessment/evaluation
- Action plan/communication

17:00 END OF DAY 2

DAY 3

13:00 SESSION 3

SIGNAL MANAGEMENT – REGULATORY EXPECTATIONS

- Review of worldwide regulatory guidance
  - USA, Switzerland, Canada, Australia, Taiwan, Saudi Arabia
- Legal basis in the EU
  - GVP Module IX
  - Signal management process at EMA
  - Signal cycle at PRAC
  - Scientific guidance on signal detection
  - MAH role and responsibilities
  - EV access
- Link with other EU processes
  - PSUR/PBRER per E2C (R2)
  - Risk Management Plan (EU-RMP)
  - Company Core Data Sheet (CCDS/CCSI)

15:00 BREAK

15:30 SESSION 3 (CONTINUED)

SIGNAL MANAGEMENT – REGULATORY EXPECTATIONS

- How to handle signals coming from authorities
  - FDA Adverse Event Reporting System (FAERS)
  - PRAC
- Incoming signals – do's and don'ts
- Group exercise on signal management

17:00 END OF DAY 3

DAY 4

13:00 SESSION 4

SIGNAL MANAGEMENT PROCESS – STRATEGY FOR IMPLEMENTATION

- Overview of signal management process issues
  - Reporting, archiving, labelling changes, tools etc.
- Implications of EVDAS access
  - Principles of MAH access to EVDAS
  - electronic Reaction Monitoring Report (eRMR) and reference periods
  - Line listing
  - Individual Case Safety Report (ICSR) form, L2B access

15:00 BREAK

15:30 SESSION 4 (CONTINUED)

SIGNAL MANAGEMENT PROCESS – STRATEGY FOR IMPLEMENTATION

- Approaches for small and large companies
  - Company differences
- Example of a signal management process
- Group exercise on signal management processes

17:00 END OF THE TRAINING COURSE

Group Discounts

Register 3 individuals from the same company for the same course and receive complimentary registration for a 4th!*

To take advantage of this offer, please print the registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together via email to basel@diaglobal.org.

**Terms and Conditions apply. Please contact DIA EMEA office for more information.*

Customized Professional Development for Your Team

Get a customized training for your department (or even across different departments!) and benefit from increased:

- Knowledge of a topic of your choice
- Flexibility & Convenience
- Cost Effectiveness

Or explore eLearning to allow self-paced learning.

For more information please contact basel@diaglobal.org

About DIA

DIA is the global connector in the life sciences product development process. Our association of more than 18,000 members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

DIA is an independent, non-profit organisation has its Global Center in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China.

Technical Requirements

To test your system compatibility, please click on the link: https://diaglobal.zoom.us/test

For further information on system requirements, please visit the website:
https://www.diaglobal.org/General/System-Requirements

Continuing Education

Please note: Most EU countries accept direct submission, by the participant, of training courses, conferences and other educational opportunities with the aim of obtaining CPD (Continuous Professional Development) points. Please do not hesitate to contact DIA directly if you need any further documentation to conclude your submission.

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 13.50 credits.

REGISTRATION FORM

Signal Management in PV | Virtual Live Training Course | # 25549
24-27 November 2025 | 13:00-17:00 CET

DIA LEARNING

REGISTRATION FEES

Registration fee includes full admission to virtual course, electronic access to training course materials. **Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the material.** Please check:

FEES	MEMBER EARLY-BIRD valid until 29 Sep 2025	MEMBER valid from 30 Sep 2025	NON-MEMBER
INDUSTRY/ REPRESENTATIVE	€ 1'420.00 ❑	€ 1'580.00 ❑	€ 1'840.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 790.00 ❑	€ 1'050.00 ❑
A special discount is available for organisations which are listed in the EMA SME register. Number of discounted seats are limited.			

All registration fees are subject to VAT if applicable.

Please enter your company's VAT number: _____

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

Payment is due 30 days after registration and must be paid in full by commencement of the course.

DIA MEMBERSHIP

All nonmember fees include a one year DIA membership, at no additional cost. Explore membership benefits at DIAglobal.org/Membership.

DIA membership will renew automatically at the end of the complimentary membership term, at the then current membership rates. You may cancel automatic membership renewal at any time by accessing your account online at DIAglobal.org. If you would like to decline complimentary membership, please indicate your preference below.

❑ **I would like to decline a one year complimentary DIA membership.**

The DIA Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 09:00 and 17:00 CE(S)T. **Tel.** :+41 61 225 51 51

Email: Basel@DIAglobal.org Mail: DIA, Küchengasse 16, 4051 Basel, Switzerland
Web: www.DIAglobal.org

TERMS AND CONDITIONS

Cancellation Policy
All cancellations must be made in writing and be received at the DIA office four weeks prior to the event start date. Cancellations are subject to an administrative fee:
- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00

If you do not cancel four weeks prior to the event start date and do not attend, you will be responsible for the full registration fee.

DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

Transfer Policy
You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA office of any such substitutions as soon as possible.

Event Stream and Recording
If you attend a DIA event, we make video and audio recordings of events (both face-to-face and online) that may include your participation in the event, including your image, questions and comments. To view our full photography and video recording policy, click https://www.diaglobal.org/general/photography-policy.

Privacy Policy
DIA respects the privacy of all of its members and customers. To view our privacy policy, click https://www.diaglobal.org/about-us/privacy-policy.

ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Job Title

Company

Address

Postal Code

City

Country

Telephone Number

Attendee email required for course material access

PAYMENT METHOD

DIA accepts only Credit Card as a payment method.

Payments by VISA, Mastercard or AMEX are accepted. Other types of credit card are not accepted.

You will receive a payment link in the coming days to complete the payment.

Please complete payment within 7 days of receipt of the payment link.

Payments will be net of all charges and bank charges will be borne by the payer.

If you have not received your confirmation within five working days, please contact basel@diaglobal.org.

By signing below, I confirm that I read and agree with DIA's Terms and Conditions of booking.

These are available from the office or online by clicking:

http://www.diaglobal.org/EUterms

Date	Signature